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REMARKS

Claims 1-37 are pending in the application, and Claims 23-37 have been withdrawn from consideration. Claims 1-22 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement and under 35 U.S.C. § 112, second paragraph as being indefinite.

It is initially noted that no prior art has been cited against the pending claims. Claim 17 has been amended to correct the typographical error noted in the Action, and the specification has been amended to delete the embedded hyperlink on page 9. Accordingly, Applicants request that the object to the specification and Claim 17 be withdrawn.

The rejections under § 112 are respectfully traversed. The rejections are discussed below.

Rejections under 35 U.S.C. § 112, First Paragraph

Reconsideration of the enablement rejection is requested in light of the *Wands* factors as specified in MPEP2164.01(a). As correctly noted by the Examiner, the *Wands* factors are: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) the level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Each of these are addressed below:

(A) The breadth of the claims. The claims are method claims, directed to computer-based screening of a nucleic acid sequence for efficient translation in a predetermined host, carried out with well-known method or readily implemented steps such as determining binding strength steps, to provide information indicating that the substrate nucleic acid sequence is a candidate for efficient translation in the host. In this context, it is submitted that the claims are not overly broad.

(B) The nature of the invention. The present claims are computer based method claims for screening a nucleic acid sequence. Method claims have by long established practice been

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accorded broad scope of enablement. The claims are a combination of steps, and combination claims have also by established practice been accorded broad scope of enablement. For both these reasons, it is submitted that this factor weighs in favor of the Applicants.

(C) The state of the prior art. The art of determining binding strengths of nucleic acid sequences and the art of computer programming are well-developed and provide a vast body of resources to which skilled persons can refer as an aid to practicing the present invention. Hence it is submitted that this factor weighs in favor of the Applicants.

(D) The level of one of ordinary skill. "When an invention, in its different aspects, involves distinct arts, the specification is enabling if it enables those skilled in each art, to carry out the aspect proper to their specialty." M.P.E.P. § 2164.05(b). The level of ordinary skill in the relevant arts are high. For nucleic acid sequence binding strengths, the level of ordinary skill in the art would encompass at least a Ph.D. coupled with post-doctoral or industry experience. For computer programming, the level of ordinary skill would encompass at least a computer science degree and industry experience. Since persons seeking to practice this invention possess great expertise, it is submitted that this factor weighs in favor of the Applicants as well.

(E) The level of predictability in the art. This art is predictable. Unlike certain fields of biotechnology and pharmaceutical arts, which are generally considered highly unpredictable, the various techniques for determining binding strengths (physical chemistry) and/or computer programming techniques are well-known and understood. Moreover, as established by the MPEP and the *Wands* factors, this is not the sole or even the dispositive inquiry in determining enablement. Hence, this factor weighs in favor of the Applicants.

(F) The amount of direction provided by the inventor. Considerable direction is given throughout the specification, including a working example beginning on page 19.

The Action notes that "the specification provides no computer code to execute the method." However, the specification provides considerable guidance regarding the functionality of the computer code to perform the method, including various flowchart figures. According to the M.P.E.P §2106 (V)(A)(2), "Applicants should be encouraged to functionally define the steps the computer will perform rather than simply reciting source or

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object code instructions." Moreover, computer code is not required to satisfy the enablement requirement. For example, in *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir. 1990), the Federal Circuit reversed a district court's determination that the patent specification did not contain an enabling disclosure of the software program used to carry out the claimed invention. The Federal Circuit noted that the claimed invention was "not in the details of the program writing, but in the apparatus and method whose patentability is based on the claimed combination of components or steps." *Id.* at 1329. Accordingly, this factor weighs in favor of Applicants.

(G) The existence of working examples. As noted in the Action, a working example of the method is provided beginning on page 19. It is also emphasized that, even in unpredictable arts, working examples are not required to satisfy the enablement requirement. *In re Strahilevitz*, 668 F.2d 1229, 212 USPQ 561 (CCPA 1982). The Action states, "When is the pattern periodic enough to indicate the nucleic acid sequence is a candidate for efficient translation to a host?" Applicant notes that step (h) states "the presence of said three base periodic binding strength cycle and phase through said substrate nucleic acid sequence indicating said substrate nucleic acid sequence is a candidate for efficient translation in said host." Accordingly, an increased presence of three base periodic binding strength cycle and phase through the substrate nucleic acid sequence indicates an increased probability that the nucleic acid sequence is a candidate for efficient translation.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Various techniques for determining the binding strength of nucleic acid sequences are known. As discussed above, an increased presence of three base periodic binding strength cycle and phase through the substrate nucleic acid sequence indicates an increased probability that the nucleic acid sequence is a candidate for efficient translation. Various programming techniques are also routine to those skilled in the art. Accordingly, it is respectfully submitted that experimentation required to determine how to practice the instant invention would be routine to persons skilled in this art.

For the foregoing reasons, it is respectfully submitted that the instant claims satisfy the requirements of 35 USC 112, first paragraph, and respectfully submitted that this rejection should be withdrawn.

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Rejections 35 U.S.C. § 112, Second Paragraph

The above claim amendments have been made to address the rejection under 35 U.S.C. § 112, second paragraph, and do not relate to issues concerning prior art.

Applicants submit that the term "periodic cycle and phase" (page 6 of the Action) satisfies the requirements of § 112. The term "periodic" is easily understood, and a limitation regarding the type or degree of periodicity is not required.

Regarding the last paragraph of page 6 of the Action, Claim 8 recites "repeating steps (c) through (j)..." Accordingly, steps (c) through (j) can be repeated once or any number of times, such as recited in Claim 10. Applicants submit that Claim 8 as amended satisfies the requirements of § 112.

With respect to the second full paragraph of page 7 of the Action, Applicants submit that a limitation on the level of efficiency of translation required to meet the limitation of the claim and terminate the repeating steps is not necessary to meet the requirements under § 112. For example, a desired level of efficiency of translation may vary depending on a particular application or environment.

Regarding the fourth full paragraph on page 7 of the Action, reference is made to page 15, line 22 to page 16, line 3 and Figure 11, which illustrates how summation can be used to determine binding strength pattern(s).

Regarding the second paragraph on page 8 of the Action, Applicants refer to § 112, paragraph 6, which states "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Accordingly, Applicants submit that it is not "unclear whether these 'means' are intended to encompass hardware or software or some of both" as stated in the Action. It is noted that the specification describes various embodiments including data processing systems, computer

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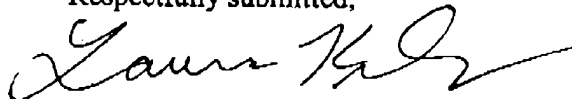
program products, entirely hardware embodiments, entirely software embodiments, and/or embodiments combining hardware and software aspects. See, e.g., page 7, lines 21-29.

In light of the above discussion and the amendments to the claims, Applicants submit that the pending claims satisfy the requirements of § 112, second paragraph, and request that the rejection be withdrawn.

Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance and respectfully requests same. The Examiner is requested to contact the undersigned to resolve any remaining issues.

Respectfully submitted,



Laura M. Kelley
Registration No. 48,441

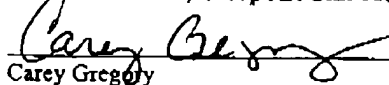
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Myers Bigel Sibley & Sajovec
P.O. Box 37428
Raleigh, NC 27627
(919) 854-1400 phone
(919) 854-1401 fax

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